



ATTACHMENT C

REMARKS

By this amendment, Applicants make minor changes to the claims in accordance with the previous election, and make amendments to the specification in the manner as suggested by the Examiner. In particular, Applicants have amended Claims 9 and 16, respectively, in such a manner as to relate to antibodies capable of binding to the specific sequence SEQ ID NO: 13 and to the A domain of SEQ ID NO: 13, and have utilized the exact language that the USPTO has determined is in compliance with the written description requirement under 35 U.S.C. §112. The amendments to the specification and claims include reference to the A domain of SEQ ID NO: 13 which is disclosed at page 54 of the specification wherein the bold portion of SEQ ID NO: 13 was described as the A domain for that protein. The bold portion of the amino acid sequence SEQ ID NO: 13 correctly shows the A domain, but this sequence was inadvertently listed in the specification as from amino acids 33-590 when in fact as clearly shown in the sequence, the A domain goes from amino acid 33 to 592, and this passage in the specification has now been corrected. Other amendments include the cancellation without prejudice of Claim 14 and the amendment to Claim 22 in accordance with the Examiner's suggestions. In light of the present amendments, Applicants submit that the present application has been placed in condition for immediate allowance for reasons as set forth in more detail below.

In the Official Action, the Examiner made an objection to the specification with regard to the use of embedded hyperlinks, and Applicants have overcome this objection in the attached amendments. The Examiner also noted the use of Applicants' trademark MSCRAMM®, and Applicants have used this in capitalized form throughout. The generic

description of this term is described at the bottom of page 2 and the top of page 3, and thus Applicants' use of this term has been proper.

In the Official Action, the Examiner rejected Claims 9, 14, 19-26 and 28 under 35 U.S.C. §112, second paragraph, on the grounds that these claims related to proteins identified by the generic methods of the claims. Without addressing the merits of this rejection, this rejection has become moot in that the amended claims are directed to antibodies to the specific sequences of the application, and such amendments overcome this rejection. Finally, the Examiner also objected to the language previously used with regard to the antibody, and thus Applicants have incorporated the language "an isolated antibody capable of binding to ..." which the US Patent and Trademark Office has determined is suitable language under the written description requirement of 35 U.S.C. §112. This is shown in the Interim Written Description Guidelines made available on the USPTO web site (see attached excerpts) which show that the language "an isolated antibody capable of binding to ..." is considered suitable in a situation where, as here, the antigen targeted by the antibody is sufficiently characterized, and in fact the present claims provide the exact sequence of the target antigen. Accordingly, the present claims are in all respects proper under 35 U.S.C. §112, and the Examiner's objections under this provision, insofar as applied to the claims as amended, are respectfully traversed and should be withdrawn.

In the Official Action, the Examiner rejected the claims under 35 U.S.C. §102 on the basis of the Choi US and PCT patent references, and on the Doucette-Stamm US Patent. In all cases, these references relate only to theoretical sequences created by computer algorithms, and not to any actual protein disclosed or expressed from such sequences, much less any antibodies that could bind to such sequences. Moreover, these references do not

disclose or suggest the A domain to any such computer-generated sequences. Accordingly, for reasons as described further below, these references do not disclose or suggest the presently claimed invention relating to isolated antibodies capable of binding the EF 1093 protein or its A domain.

In short, all of the cited references, including the Choi references and the Doucette-Stamm patent, are merely “paper patents”, i.e., they reflect the sequencing of large amounts of the bacterial genome, and such sequencing and the projection of possible proteins was done solely through a series of computer algorithms. As a result, there is not a single protein reflected in these references which was actually expressed and/or tested with regard to any characteristics, such as antigenicity. Accordingly, these patents are totally silent as to whether any of the purported polypeptides could even be expressed, whether the expressed product would be stable, or whether the expressed product would be immunogenic, and thus no information is provided which would indicate anything about any of the properties of the predicted proteins and polypeptides in these references, much less any information about whether any antibodies could be generated thereby. Even further, there is no disclosure or suggestion of any specific regions within the purported polypeptides, and thus there is no disclosure of any A domains of any polypeptides, much less any disclosure of any antibody that could bind to the A domains.

In total contrast to these references, the present application not only reflects the actual isolation of particular proteins and polypeptides generated by the method of the present invention, Applicants actually generated antibodies to the actual proteins and polypeptides. Moreover, as recognized by the Examiner, at minimum, the present specification reflects that the present antibodies can be utilized in the treatment of *E. faecalis* infections, whereas to the

contrary, the Choi and Doucette-Stamm references do not lead one to select any particular polypeptide to generate antibodies from, much less one that will be effective in treating infection. Even further, as reflected above, there would be no teaching or suggestion as to which protein or polypeptide could actually be generated from the predicted computer algorithm sequences, much less any teaching or suggestion as to which ones would be stable or immunogenic, and thus there is no disclosure or suggestion whatsoever in any of the cited references by which one would be able to obtain the particular antibodies of the present claims.

Applicants thus submit that the claims in their present form are patentable over the Choi and Doucette-Stamm references, and that the Examiner's rejections on the basis of the prior art, insofar as applied to the claims as amended, is respectfully traversed and should be withdrawn.

One final rejection was made to Claim 22 on the basis of enablement, but at the same time the Examiner conceded that this claim would be enabled with regard to the treatment of *E. faecalis* infection. Accordingly, without addressing the merits of this rejection, and solely for the purpose of expediting prosecution and allowance of the present application, Applicants herein amend Claim 22 in the manner considered enabled by the Examiner, and the Examiner's rejection on this basis has become moot.

Applicants thus submit that in light of the amendments and arguments as set forth above, the present application has now been placed in condition for immediate allowance, and such action is respectfully requested.

END OF REMARKS